

Testimony SB 198 – Expansion of the Drug Repository Program

August 18, 2009

Thank you Chair Erpenbach and committee members for holding this hearing today on Senate Bill 198 to enhance Wisconsin's drug repository law.

The Department of Health Services administers the drug repository program that is now limited to cancer drugs and prescription drugs and supplies for chronic illness. These unused medications help the uninsured and indigent receive needed, but costly, prescription drugs.

This bill expands the program to allow the donation of <u>all</u> drugs and supplies with certain exceptions, such as controlled substances. The bill provides safety requirements and protections for these prescription drugs to be re-cycled. Only qualified individuals can dispense these donated drugs and supplies. Expired drugs are not accepted under the program and the drugs must be in their original, sealed, tamper-proof packaging.

When medications are no longer needed by a patient, it is cost-effective to re-dispense them for the benefit of patients without access to health care coverage to pay for these medications. Without this program, these drugs would be destroyed or sent to the landfill.

The idea for this program came from Mike Dow, a pharmacist and volunteer at the Janesville's HealthNet, a free clinic in my district. He noted that pharmacies get a lot of prescription returns from nursing facilities and they are unable to credit them for the returns. They have already billed for those prescriptions and many private insurance companies do not have a mechanism to issue credits for them. Consequently, the pharmacy cannot resell these medications because that would be fraud. Therefore, according to law they must dispose of them.

However, under the proposed new bill, they could donate these medications to free clinics, like HealthNet.

This is a safe source of drugs because each tablet or capsule has its own place in the package and each package has been filled and initialed by a pharmacist and pharmacy technician. The package also includes the name and strength of the drug, the lot number and the expiration date.

There is currently shortage of medications. While free clinics can dispense physician samples and drugs donated by manufacturers, the supply is not sufficient to meet increasing demand. This bill would help fill that gap.

I urge the committee to support SB 198 and its companion, AB 272, introduced by Rep. John Nygren. Thank you.



"Leading Our Profession in a Changing Health Care Environment"

Tom Engels, Vice President of Public Affairs, Pharmacy Society of Wisconsin

Testimony before the Senate committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue in Support of Senate Bill 198

Tuesday, August 18, 2009

Thank you chairman Erpenbach and members of the Senate committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue for this opportunity to testify in support of Senate Bill 198. I would also like to Senator Judy Robson, author of Senate Bill 198 and Representative John Nygren, author of the companion bill AB 272 for their support.

The changes recommended by this legislation will amend current Wisconsin laws related to the operations of the cancer and chronic disease prescription drug repository programs. These changes are based on the experiences of Wisconsin pharmacists that are involved in free health clinics located in Senator Robson's and Representative Nygren's legislative districts that see patients in need of medications, but are limited by the programs restrictions. We believe this legislation will expand the options available to patients and health care providers.

Cancer and Chronic Disease Drug Repository Programs

The current drug repository programs were started in 2005 and have experienced only moderate success. There are fewer than 30 pharmacies or medical facilities registered with the Department of Health Services to participate in the programs. (List attached)

Under these programs, any person may donate an unused prescription drug used to treat cancer or the side effects of cancer or a chronic disease. The legislation defines chronic diseases as any illness, impairment or other physical condition, other than cancer, that requires health care and treatment over a prolonged period and, although amenable to treatment, frequently progresses to increasing disability or death.

The program includes strict criterion for donated medications to ensure their integrity and for the safety of patients receiving the medications.

- > Participation is voluntary by a pharmacy or a medical facility. Even if a pharmacy chooses to participate in the program(s) they can refuse to accept a donated prescription drug if they question its integrity.
- ➤ Both programs require the pharmacy or medical facility to perform an inspection of all donated items. The cancer drug or chronic disease drug or supplies must be in their original, unopened, sealed and tamper-evident unit dose packaging. If the drug is packaged in single-unit doses, then the single unit dose must be unopened.
- > The donated drugs or supplies are not adulterated or misbranded as determined by a pharmacist. The drug's expiration date must be at least six months later than the date the drug was donated.
- ➤ Additionally, donated prescription medications can not be a registered DEA controlled substance.

From the beginning, PSW raised conceptual concerns with the programs but supported their creation with reservations. Here are a few of the problems identified by pharmacy providers with the current repository programs.

- Soon after the enactment of the law creating these programs, individuals would come into pharmacies with medications expecting to be able to donate the items even though the pharmacy had not opted to participate in the repository programs.
- People came into the pharmacy with bags of unused medications expecting to be able to donate the medications. However, of the medications brought to pharmacies; most did not qualify because they were dispensed in vials or were controlled substances.
- In many cases, individuals would simply leave the unused medications at the pharmacy which required the pharmacy to make arrangements for their disposal.
- Most people cannot identify whether or not a medication is a controlled substance, furthermore they are not aware of the federal law that prohibits pharmacies from accepting these medications.
- Pharmacies participating in the program are unable to track available medications for qualified patients, other pharmacies or prescribing practitioners. This inability to track medications results in many donated items later being disposed of because they are not used.

I would like to emphasize that the Pharmacy Society of Wisconsin supports these programs but believes they must be amended. Senate Bill 198 makes some of those changes by allowing for more medications to be made available for donation.

Unfortunately, the changes recommended by this legislation won't go far enough to address the problems with the current programs. For instance, due to limited financial resources, SB 198 will not have a tracking system which lists the available donated medications and where they can be obtained. The Pharmacy Society of Wisconsin hopes that someday the Wisconsin repository programs can incorporate a tracking system that is similar to that used in the neighboring State of Iowa.

Although this legislation is not perfect it is a step in the right direction and we urge you to support SB 198.

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Name of Pharmacy or Medical Facility Bohlman Drugstore, Inc. Dennis L. Hunt Pharmacy, Inc. DBA Omro Pharmacy Stoxen Professional Pharmacy Larson-Mayer Pharmacy Larson-Mayer Pharmacy Larson-Mayer Pharmacy Marshfield Clinic Pharmacy Minoqua Center Marshfield Clinic Pharmacy Wausua Center Marshfield Clinic Pharmacy Wausua Center Marshfield Clinic Pharmacy Wausua Center Marshfield Clinic Pharmacy Werrill Center Marshfield Clinic Pharmacy Merrill Center Marshfield Clinic Pharmacy Weston Center Marshfield Clinic Pharmacy Hoston C	

S.T.E.P.S. At-A-Glance

Initial Prescription

- 1. Counsel and perform pregnancy testing (if applicable)
- 2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
- 3. Complete, print, and sign Patient Registration/Patient-Physician Agreement Form
 - Males (adults and children)
 - Females of childbearing potential include females who have not undergone a natural menopause for at least 24 months
 - Adult females not of childbearing potential include females who have had a natural menopause for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy
- 4. Fax Patient Registration/Patient-Physician Agreement Form to 1-888-432-9325
- 5. Instruct patient to complete phone survey by calling 1-888-423-5436 prior to prescriber obtaining an authorization number
 - All males: Patient Registration/Patient-Physician Agreement Form is considered the initial phone survey
 - All females: Complete the appropriate phone survey
- Complete a prescriber phone survey by calling 1-888-423-5436, and obtain a new authorization number for each prescription
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
- 7. Write the authorization number on the prescription; prescription and authorization number are valid only for 7 days
- 8. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Subsequent Prescriptions

- 1. Perform scheduled pregnancy testing (if applicable)
- 2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraception. Patients should be instructed to not extensively handle or open THALOMID® (thalidomide) Capsules and to maintain storage of capsules in blister packs until ingestion
- 3. Instruct patient to complete surveys **as scheduled**, prior to prescriber obtaining an authorization number and filling prescription
 - Monthly:
 - · Males (adults and children)
 - Females of childbearing potential (adults and children), female children not of childbearing potential
 - Every 6 months:
 - Adult females not of childbearing potential (if had natural menopause for more than 24 consecutive months, a hysterectomy, or bilateral oophorectomy)
- 4. Complete a prescriber phone survey, which should be done on the day the prescription is written
 - You will need to enter the following information:
 - Prescriber's DEA number or Social Security number
 - · Patient's Social Security number
 - Date and result of patient's last pregnancy test (if applicable); valid only for 7 days
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
- Obtain authorization number for each new prescription; faxed prescriptions are permissible if state law allows

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- Write the authorization number on the new prescription; prescription and authorization number are valid only for 7 days
- 7. If drug is not dispensed within 7 days, surveys must be repeated. To cancel authorization number(s), call 1-888-423-5436

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



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Chairman Erpenbach and Committee Members,

Hello! My name is Bill Clement and I own three pharmacies in Northeast Wisconsin. One pharmacy is called Peshtigo Pharmacy and the second is Oconto Pharmacy. The third one, Peshtigo Pharmacy Health Care Services, is a long term care pharmacy that services area nursing facilities. I am also on the Board of Directors for the Twin County Free Clinic in Marinette, WI. We provide free physician care and prescriptions to poor and needy people. When we have our meetings, a large concern of ours is the high cost of medications. We have fourteen people on our board and I always feel like I should be doing more to reduce pharmacy costs since I am a pharmacist. We get a lot of prescription returns from facilities and are unable to credit them for the returns. We have already billed these prescriptions out and many private insurance companies do not have a mechanism to issue a credit for them. Consequently, we cannot resell these medications because it would be fraud, and they must be disposed of, according to the law. However, under the proposed new bill we could donate these medications to the "free clinic".

Medications are sent to the nursing facilities in thirty-one day supply bubble packages. Each tablet or capsule has its own individual place in the package and each package has been filled and initialed on the back by a pharmacist and a pharmacy technician. The package back also includes the name and strength of the drug, lot number and expiration date.

These medications come back to us from the nursing facilities for many reasons. The doctor may change the drug or the strength, the patient may suffer a drug reaction or interaction, or the patient may pass away. The medications left in the package are perfectly good and, since each tablet or capsule is enclosed in an individual bubble, they are untouched.

I talked to Mr John Nygren, our state representative, regarding my concern about this excessive waste and the lack of funds for medications at our free clinic. He was very concerned and suggested enacting a law to correct the waste. In conclusion I hope you will strongly support this bill sponsored by Mr. Nygren.

Sincerely,

R. William Clement, R. Ph..



Testimony Senate Bill 198 – Drug Repository Program Representative John Nygren August 18, 2009

Thank you Chair Erpenbach and members of the Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue for holding a public hearing on Senate Bill 198 today. I apologize for not appearing in person, but please don't hesitate to contact my office if I can be of any assistance.

In April 2004, Governor Doyle signed Nick's Law or AB 845 into law creating a cancer drug repository program. Nick's Law was named after Nick Scavone who battled cancer for 20 years. After Scavone's death his wife Barbara, tried to donate his unused medications and supplies – worth \$2,000 by her estimation. Though the drugs and supplies were sealed in their original packaging, she was told to dispose of the medication and throw the supplies away. She later joined forces with the American Cancer Society to pass "Nick's Law."

The following year in July of 2005, Governor Doyle signed AB 197 into law, expanding the Cancer Drug Repository Program to include Prescription Drugs and Supplies for Chronic Diseases.

Currently, cancer and chronic disease patients may donate unused medications and supplies to a participating pharmacy or medical facility. Those items are then recertified and given to individuals with cancer or chronic disease that do not have insurance or are underinsured. At present, 28 Pharmacies and Medical facilities participate in the program.

The idea for this legislation arose from suggestions from a constituent of mine, Bill Clement, who owns and operates three pharmacies and is on the board of directors of the Twin Counties Free Clinic of Marinette, WI and Mr. Mike Dow, a Pharmacist and President of Janesville's Healthnet. Mr. Clement and Mr. Dow, as pharmacists, indicated the need to expand the current Cancer and Chronic Disease Drug Repository Program to include other prescription drugs, to help assist free clinics and their patients. With the help of Bill, Mike, Tom Engles of

the Pharmacy Society, and Senator Robson I drafted this legislation to expand the current Drug Repository Program to help maximize participation and assist more low income individuals.

At present, Free Clinics dispense a combination of physician samples and drugs donated by manufacturers to patients who do not have any form of health coverage. However, the supply of these drugs is not sufficient enough to meet increasing demand. Free clinics have pharmacists, like Bill and Mike, who handle drug utilization review and dispensing. Free clinics, under law, can not accept, store, or dispense controlled substances.

This bill would expand the program to allow for the donation of all drugs and supplies, with certain limited exceptions, to pharmacies and medical facilities. Common sense protections continue to be in place under this bill so only qualified individuals can dispense the drugs and supplies. Protections to ensure no expired or tampered drugs are accepted under the program are in place as well.

When drugs are no longer useful to a patient, it is better to reuse them for the benefit of needy patients than to flush them or send them to a landfill. The drug repository program and the changes included in this bill assist our neediest citizens at a time when they are in need of medical care.

Governor Doyle stated in a news release when he signed AB 197 into law on July 5, 2005, "I'm pleased to sign a bill that will further our efforts to provide access to quality health care for all citizens in Wisconsin... The cancer drug repository will help families who can least afford it to get the life-saving drugs that they need. It is an innovative effort but it can only work if people know about it, people donate to it, and people use it. I'm calling on pharmacists, physicians, families, and patients to donate unused drugs and participate in this program."

Today, I am echoing Governor Doyle's call to help families who can least afford it to help them get the drugs they need. I encourage you to support Senate Bill 198 for passage. If you have any questions, please don't hesitate to contact me I. Thank you!